REMARKS

Reconsideration of this Application is respectfully requested.

Claims 1-6, 13-15, 20-21, and 26 are pending in the application, with 1 and 26 being the independent claims. The claim amendments are supported in the instant specification at pages 8, 11-14, and 16-17 and no new matter has been added.

Based upon the foregoing Amendments, attached Declaration, and following Remarks, the applicants respectfully request the Examiner reconsider all outstanding rejections, and that they be withdrawn.

Rejection under 35 U.S.C. § 112, 1st paragraph – Claims 13-14

Claims 13-14 stand rejected under 35 U.S.C. §112, 1st paragraph, as failing to comply with the written description requirement. The Examiner asserts that the specification and claims lack sufficient written description of the polynucleotide encoding the hybrid polypeptide; there is no description of the nucleic acids that must encode the hybrid polypeptide; the specification does not provide for the structure of the polynucleotide; and the specification does not provide a teaching of the entire structure, showing that nucleic acids were isolated at the time the invention was made.

Applicants respectfully traverse this rejection. The attached 37 C.F.R. §1.132 declaration is herewith submitted to traverse the rejection. As evident from the attached declaration, Dr. Rudolf Valenta attests to the fact that at the time the invention was made, the polynucleotide and polypeptide sequences for the timothy grass pollen allergens were available in the art. As evident from the Exhibits attached to the declaration, Phl p1 was disclosed in the Peterson, *et al.* reference in 1995, Phl p2 was disclosed in an article authored by Dr. Valenta in 1993, Phl p5 was disclosed in an article authored by Dr. Valenta in 1993, and Phl p6 was disclosed in an article authored by Dr. Valenta in 1999. Therefore, all of the timothy pollen sequences were known at the time the invention was made and prior to the filing date of the instant application.

Dr. Valenta also declares that one of ordinary skill in the art, armed with the instant specification, would understand the sequences used in the present invention. As evident from the specification, the applicants had isolated the nucleic acid sequences and had possession of the claimed hybrid polypeptides. The applicants describe the construction of the hybrid polypeptides in Examples 2 and 3 of the specification. Specifically, the specification sets forth the method of constructing the plasmids and the method of expressing and purifying the hybrid polypeptides. *See* Examples 2 and 3, pp. 11-14. The applicants also provide examples showing the assays used to determine the activity of the hybrid polypeptides in comparison to individual allergenic proteins. *See* Examples 4, 5 , and 6, pp. 14-17. Therefore, the instant application satisfies the written description requirement for the claimed hybrid polypeptides and method for preparing hybrid polypeptides.

Applicants respectfully request reconsideration of this rejection and withdrawal of these grounds of rejection in view of the aforementioned remarks. Applicants submit that the pending claims satisfy the written description requirement.

Rejection under 35 U.S.C. § 112, 1st paragraph – Claims 1-6, 13-15, 20-21 and 26

Claims 1-6, 13-15, 20-21 and 26 stand rejected under 35 U.S.C. §112, 1st paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims drawn to the fragments thereof, wherein the fragments consist of amino acid sequences that fail to recite any associate function and that it is unclear how to define fragments thereof with respect to what amino acids must be comprised therein to acquire the appropriate fragments. Therefore, the Examiner asserts that the claims lack an adequate description of both the fragments thereof and the function of the polypeptide.

Applicants respectfully traverse this rejection. The claims have been amended to recite the associated function of inducing an antibody response as supported throughout the specification and in particular pages 8 and 16-17. The amino acids of the present

invention for the fragments, as described in the claims, are at least 8 consecutive amino acids that result in inducing an antibody response. The specification defines "allergenic proteins or fragments thereof" as comprising "modifications of the allergens wherein the sequence of the naturally occurring allergen has been slightly modified by substitutions of single amino acids or nucleotides whereby the allergenic potential has been substantially maintained." *See* Specification, p. 2. Further, the specification specifically states that "when fragments of allergenic proteins are employed it is possible to prepare a hybrid polypeptide comprising only fragments which have an allergenic activity which is lower compared with the respective allergenic proteins from which they are derived." *See* Specification, p. 3. The inventors continue on to explain that this lower allergenic activity could "be due to the destruction of epitopes by modified secondary or tertiary structure of the fragment compared with the full length protein." *See* Specification, p. 3. The specification discloses the activity of various antigenic proteins and hybrid polypeptides illustrating that the applicants invented the hybrid polypeptide and had possession of the invention at the time the application was filed.

In *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), the court states that the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date, the applicant was in possession of the invention. In light of the declaration signed by Dr. Valenta, regarding the availability of the sequences for the allergenic proteins Phl p1, Phl p2, Phl p5, and Phl p6, one of ordinary skill in the art, aided by the instant specification, would understand the fragments thereof encompassed by the claims based upon the fact that the allergenic potential is maintained and the resulting hybrid polypeptide induces an antibody response. Therefore, the applicants have conveyed with clarity to those skilled in the art that they were in possession of the invention.

Applicants respectfully request reconsideration of this rejection and withdrawal of these grounds of rejection in view of the aforementioned remarks. Applicants submit that the pending claims satisfy the written description requirement.

Rejection under 35 U.S.C. § 102 (b) – Vrtala et al.

Claims 1-3, and 13-14 stand rejected under 35 U.S.C. §102(b) as being anticipated by Vrtala, *et al.* (1996, J. Allergy Clin. Immun., Vol. 97(3):781-787). The Examiner asserts that the reference teaches a hybrid polypeptide comprising at least two different allergenic proteins, specifically Phl p1 and Phl p2 and that these are the complete allergenic proteins as the cDNA used for encoding the mature protein. The Examiner also asserts that the reference teaches a polynucleotide, which encodes a polypeptide that meets the clamed limitations and a method for preparing a hybrid polypeptide using PCR technology comprising the same steps as recited by the instant claims.

Applicants respectfully traverse this rejection. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, if a prior art reference does not teach each and every claim element, it does not anticipate the claim.

The Vrtala, *et al.* reference does not teach a hybrid polypeptide as asserted by the Examiner. The 37 C.F.R. §1.132 declaration, herewith attached, attested to by Dr. Valenta states that Dr. Valenta is an author of the Vrtala, *et al.* reference and that it does not describe or teach a hybrid polypeptide using timothy grass pollens, but rather only teaches the allergens individually. As such, the reference does not teach each and every claim element and therefore is not anticipated by the Vrtala, *et al.* reference.

Applicants respectfully request reconsideration of this rejection and withdrawal of these grounds of rejection in view of the aforementioned remarks. Applicants submit that the pending claims are not anticipated.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office action and, as such, the present application is in condition for allowance. Applicants wish to expedite the prosecution process and if the Examiner believes, for any reason that personal communication will help expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Response is respectfully requested.

Respectfully submitted,

REED SMITH, LLP

By: Toni-Junell Herbert
Toni-Junell Herbert
Reg. No. 34,348 ECF

Date: Oct. 4, 2004

1301 K Street, N.W.
Suite 1100-East Tower
Washington, D.C. 20005
(202) 414-9200

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Linhart, et al.

Art Unit: 1645

Serial No. 10/026,914

Examiner: Jana A. Hines

Filed: 12/27/01

Atty. Docket: 966927.00006

For: Allergy Vaccines Containing Hybrid Polypeptides

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Rudolf Valenta, M.D., state that I am one of the named inventors in the above-referenced application, and hereby declare and state:

1. I have read the Office action mailed on July 2, 2004 in the above-referenced application.

2. I am one of the authors of the Vrtala, et al. reference (1996, J. Allergy Clin. Immun., Vol. 97(3):781-787) cited by Examiner Jana A. Hines in the Office action mailed on July 2, 2004.

3. The Vrtala, et al. reference does not describe or teach the production of a hybrid polypeptide and more specifically, does not describe or teach a hybrid polypeptide comprising two different allergenic proteins such as Phl p1 and Phl p2.

4. The Vrtala, et al. reference only reports the expression of the individual allergens.

5. The cDNA and amino acid sequences for the timothy grass pollen allergens described in the instant application and namely, Phl p1, Phl p2, Phl p5, and Phl p6, were available in the art at the time the invention was made and at the filing of the instant application, which is illustrated in Exhibits 1-4, herewith attached. Further, one of ordinary skill in the art, armed with the instant application, would understand the sequences of said allergens and the claimed hybrid polypeptide invention.

6. That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents ensuing thereon.

Respectfully submitted.

Date: Sept 28, 2004

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32256
PATENT TRADEMARK OFFICE

1301 K Street, N.W.
Suite 1100 – East Tower
Washington, DC 20005
Tel. 202-414-9200

☐ **1:** Z27090. P.pratense mRNA f...[gi:3901093] Links

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LOCUS       PPRPHLP1X               1152 bp    mRNA    linear   PLN 09-SEP-2004
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ACCESSION   Z27090
VERSION     Z27090.1  GI:3901093
KEYWORDS    PhlpI; pollen allergen.
SOURCE      Phleum pratense (timothy grass)
  ORGANISM  Phleum pratense
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae;
            Pooideae; Aveneae; Phleum.
REFERENCE   1  (bases 1 to 1149)
  AUTHORS   Petersen,A., Schramm,G., Bufe,A., Schlaak,M. and Becker,W.M.
  TITLE     Structural investigations of the major allergen Phl p I on the
            complementary DNA and protein level
  JOURNAL   J. Allergy Clin. Immunol. 95 (5 Pt 1), 987-994 (1995)
  MEDLINE   95270847
   PUBMED   7751520
REFERENCE   2  (bases 1 to 1149)
  AUTHORS   Petersen,A.
  TITLE     Direct Submission
  JOURNAL   Submitted (01-NOV-1993) Petersen A., Forschungsinstitut Borstel,
            Allergology, Parkallee 22, 23845 BORSTEL, Germany
COMMENT     On Nov 21, 1998 this sequence version replaced gi:414907.
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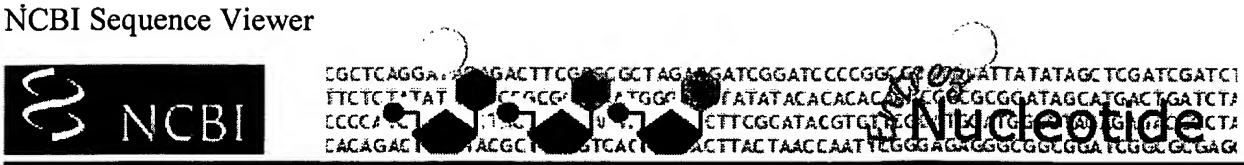

☐ 1: X75925. P.pratense mRNA f...[gi:415895] Links

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DEFINITION  P.pratense mRNA for PHL PII pollen allergen.
ACCESSION   X75925
VERSION     X75925.1  GI:415895
KEYWORDS    allergen; PhlpII.
SOURCE      Phleum pratense (timothy grass)
  ORGANISM  Phleum pratense
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae;
            Pooideae; Aveneae; Phleum.
REFERENCE   1
  AUTHORS   Dolecek,C., Vrtala,S., Laffer,S., Steinberger,P., Kraft,D.,
            Scheiner,O. and Valenta,R.
  TITLE     Molecular characterization of Phl p II, a major timothy grass
            (Phleum pratense) pollen allergen
  JOURNAL   FEBS Lett. 335 (3), 299-304 (1993)
  MEDLINE   94085541
   PUBMED   8262175
REFERENCE   2  (bases 1 to 525)
  AUTHORS   Dolecek,C.
  TITLE     Direct Submission
  JOURNAL   Submitted (05-NOV-1993) C. Dolecek, Ins. of General and Exp.
            Pathology, General Hospital, Waehringer Guertel 18-20, 1090 Vienna,
            AUSTRIA
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☐ **1:** X74735. P. pratense mRNA ...[gi:398829] Links

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DEFINITION  P. pratense mRNA for PhlpV.
ACCESSION   X74735
VERSION     X74735.1  GI:398829
KEYWORDS    allergen.
SOURCE      Phleum pratense (timothy grass)
  ORGANISM  Phleum pratense
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae;
            Pooideae; Aveneae; Phleum.
REFERENCE   1  (bases 1 to 1192)
  AUTHORS   Vrtala,S., Sperr,W.R., Reimitzer,I., van Ree,R., Laffer,S.,
            Mueller,W.D., Valent,P., Lechner,K., Rumpold,H., Kraft,D.,
            Scheiner,O. and Valenta,R.
  TITLE     cDNA cloning of a major allergen from timothy grass (Phleum
            pratense) pollen; characterization of the recombinant Phl pV
            allergen
  JOURNAL   J. Immunol. 151 (9), 4773-4781 (1993)
  MEDLINE   94014421
   PUBMED   7691956
REFERENCE   2  (bases 1 to 1192)
  AUTHORS   Vrtala,S.
  TITLE     Direct Submission
  JOURNAL   Submitted (17-AUG-1993) S. Vrtala, Institute of General &
            Experimental Pathology, Wahringer Guerel 18-20, AKH, 1090 Wien,
            AUSTRIA
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☐ 1: Y16959. Phleum pratense m...[gi:3004472] Links

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DEFINITION  Phleum pratense mRNA for Phl p6 IgE binding fragment, isolate c233.
ACCESSION   Y16959
VERSION     Y16959.1  GI:3004472
KEYWORDS    IgE binding protein.
SOURCE      Phleum pratense (timothy grass)
  ORGANISM  Phleum pratense
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae;
            Pooideae; Aveneae; Phleum.
REFERENCE   1
  AUTHORS   Vrtala,S., Fischer,S., Grote,M., Vangelista,L., Pastore,A.,
            Sperr,W.R., Valent,P., Reichelt,R., Kraft,D. and Valenta,R.
  TITLE     Molecular, immunological and structural characterization of Phl p6,
            a major allergen and P-particle-associated protein from Timothy
            grass (Phleum pratense) pollen
  JOURNAL   J. Immunol.
REFERENCE   2  (bases 1 to 474)
  AUTHORS   Vrtala,S.
  TITLE     Direct Submission
  JOURNAL   Submitted (25-MAR-1998) S. Vrtala, Institute of General and
            Experimental Pathology, Wahringer Guertel 18-20, AKH, 1090 Wien,
            AUSTRIA
COMMENT     Related sequence: Z27090.
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      421 ttgtaatcct gataagaaat gcgattaagt ccatttatga aaaaaaaaaa aaaa
//
```